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FOR: INTRALUMINAL GRAFT

ASSISTANT COMMISSIONER FOR PATENTS

ALEXANDRIA, VA 22313

37 CFR 41.37 APPEAL BRIEF

Sir:

In response to the final office action mailed August 23, 2005, and subsequent to the amendment filed after that final office action, the applicants appeal.

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**I. 37 CFR 41.37 (a)(1) and (2)**

This brief is filed with the notice of appeal under 41.31 and is accompanied by the fee set forth in 37 CFR 41.20(b)(2), and sets forth the authorities and arguments on which the appellant will rely to maintain the appeal.

**II. 37 CFR 41.37 (b)**

The filing is timely. Accordingly, this subsection is not relevant.

**III. 37 CFR 41.37 (c)(1)**

**A. 37 CFR 41.37 (c)(1)(i) Real Party in Interest**

The real parties in interest are Edwards Lifesciences, LLC, a California LLC, and Endogad PTY Ltd, an Australian Corporation.

**B. 37 CFR 41.37 (c)(1)(ii) Related Appeals and Interferences**

There are no related appeals or interferences.

**C. 37 CFR 41.37 (c)(1)(iii) Status of Claims**

Claims 12-36 are pending, rejected, and under appeal.

**D. 37 CFR 41.37 (c)(1)(iv) Status of Amendments**

We filed a 37 CFR 1.116 amendment October 27, 2005. The USPTO mailed an advisory action 11/14/2005 indicated that for purposes of appeal, the 37 CFR 1.116 amendment filed October 27, 2005 is entered. The claims appendix to this brief lists claims as amended by the 37 CFR 1.116 amendment filed October 27, 2005.

**E. 37 CFR 41.37 (c)(1)(v) Summary of the Independent Claimed Subject Matter**

The invention of claim 12 defines a prosthesis (Figs. 2, 3, 6, 7; element 10; page 8 line 35) for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising: a first end, a second end, and wherein at least one of the first and second ends is

provided with a wire structure which has a plurality of apices (Figs. 6, 7, element 17; ) extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel (page 3 lines 13-16 and page 10 lines 2-4).

The invention of claim 20 defines a prosthesis (Figs. 2, 3, 6, 7; element 10) for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising: a first end adapted for placement adjacent to a junction between the first vessel and the second vessel, and a second end, wherein the first end is reinforced with a wire member which has a plurality of apices (Figs. 6, 7, element 17) extending beyond at least a portion of the first end and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel (page 3 lines 13-16 and page 10 lines 2-4).

**F. 37 CFR 41.37 (c)(1)(vi) Grounds of Rejection to be Reviewed on Appeal**

Whether the rejections of claims 12-16, 19, 20 and 25-36 under 35 USC 102(e) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Piplani et al. (5,489,295 hereinafter Piplani) are improper and should be reversed.

Whether the rejections of claims 17 and 18 under 35 USC 103(a) as being unpatentable over Piplani in view of Kornberg (4,617,932) are improper and should be reversed.

Whether the rejections of claims 21-36 under 35 USC 102(e) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Cragg (5,665,115) are improper and should be reversed.

**G. 37 CFR 41.37 (c)(1)(vii) Argument**

**1. The Examiner's Rejections of Claims 12-16, 19, 20 and 25-36 Under 35 USC 102(e) as Anticipated by or, in the Alternative, Under 35 USC 103(a) as Obvious Over Piplani are Improper and Should be Reversed**

**2. Summary of Piplani**

In summary, Piplani discloses (see Figure 4) a bifurcated graft in which the bifurcation or crotch region is designed to span a patient's aorto-iliac arterial bifurcation. See the first sentence

in Piplani's "Summary of the Invention" section at column 1 lines 21-27, which states "graft having a bifurcation ... *traversing* an aortic bifurcation...." Emphasis supplied. Moreover, Piplani discloses the springy sections 126, 127 are only at the ends of the graft, as is shown in Figure 4. Therefore, when installed in a patient, the springy sections 126, 127 do not extend across the lumens forming the aorto-iliac bifurcation because they are not adjacent the aorto-iliac bifurcation, and because each such springy section extends from the corresponding end of the graft away from the aorto-iliac bifurcation. Thus, springy section 126 resides in the abdominal aorta upstream of the aorto-iliac bifurcation and springy section 127 resides in an iliac artery below the aorto-iliac bifurcation. Obviously, Piplani's graft 20 was designed so that the graft's leg portions 116, 117 portion would extend over the aorto-iliac bifurcation, which means that the springy sections 126 and 127 did not overlap that bifurcation. In fact, that point is implied in Piplani's abstract (by the statement that the graft is "for repairing an aneurysm in the vicinity of an aortic bifurcation").

### 3. The Examiner's Grounds for Rejection

The examiner rejects claims 12-16, 19, 20 and 25-36 under 35 USC 102(e) as allegedly anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Piplani, stating that:

Claims 12-16, 19, 20 and 25-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Piplani et al. (5,489,295). As to claims 12 and 20, Piplani et al., in figure 4, disclose prosthesis 20 wherein at least one of the first and second ends is provided with a wire structure (126 or 127) which has a plurality of apices (e.g. 132) extending beyond at least a portion of the corresponding end. The apices are inherently capable of being located across a lumen of a second vessel. *For example, viewing figure 19, if the prosthesis 20 is inserted into a patient who has arteries (shown in figure 19 extending laterally near the top of the figure) which are closer to the aortic bifurcation 221 than the example shown in figure 19, than the apices 132 on wire structure 126 would be located across the lumen*

*of each of the laterally extending arteries.* Alternatively, it would have been obvious that the apices are capable of being located across a lumen of a second vessel for this reason. *As to claims 25-30, wire structure (126 or 127) has a shape that is clearly generally sinusoidal or zig-zag even though it is not a perfect sine wave. As to claims 31-36, Piplani et al. disclose first and second wires (the lengths of platinum wires described in col. 5, lines 23-27).* [Office action mailed August 23, 2005 page 3 line 3 through page 4 line 12; text contained in this office action and not contained in the prior office action in italics and bold.]

In response, the appellant points out that the legal tests for anticipation and obviousness require showings of different elements. It follows that rejections based upon 102 should be reviewed separately from rejections based upon 103. The subsections below, after the summary of Piplani, bifurcate the 102 and 103 rejections.

**4. The Rejections of Claims 12-16, 19, 20 and 25-36 Under 35 USC 102(e) as Anticipated by Piplani are Improper and Should be Reversed**

**a. Independent Claims 12 and 20**

In response, the appellant points out that the 102 rejections are based upon an assertion of inherency. The examiner admitted that Piplani does not expressly disclose that Piplani's springy sections 126, 127 extend across a lumen of any vessel. The examiner relied upon an inherency argument to conclude that Piplani's springy sections 126, 127 extend across a lumen of an intersecting vessel. However, Piplani does not inherently disclose a springy section extended across a lumen of an intersecting vessel for the following reasons.

**b. Requirements for there to be Inherency**

The law of inherency is clear. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency.]" In re Oelrich , 666 F.2d 578,

581-82, 212 USPQ 323, 326 (CCPA 1981).

Moreover, it is equally clear that, even if the examiner were to show that the allegedly inherent feature of "apices extend across a lumen of the second vessel" were an optimal arrangement, that would support neither a 102 rejection based upon inherency nor a 103 rejection based upon obviousness:

To support the Board's affirmance of the rejection, the Commissioner points out that in the recording art, the exact matching of signal time to recording time is an optimal condition, and that this condition would be met by fulfilling the claimed relationship. While the condition described may be an optimal one, it is not "inherent" in Awamoto. Nor are the means to achieve this optimal condition disclosed by Awamoto, explicitly or implicitly. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency.]" In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981) (citations omitted) (emphasis added). "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See In re Newell, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989). [In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).]

c. **The Examiner Failed to Demonstrate Inherency of Apices  
Extending Across a Lumen**

The examiner does not even suggest that placement such that the apices extend across a lumen are an optimal feature. All the examiner asserts is that this feature is inherent because *the examiner can conceive of* a prophetic example in which the apices extend across a lumen, stating that:



The apices are inherently capable of being located across a lumen of a second vessel. *For example, viewing figure 19, if the prosthesis 20 is inserted into a patient who has arteries (shown in figure 19 extending laterally near the top of the figure) which are closer to the aortic bifurcation 221 than the example shown in figure 19, than the apices 132 on wire structure 126 would be located across the lumen of each of the laterally extending arteries.*

The examiner's ability to conceive of a prophetic example does not support inherency. Moreover, the last paragraph of Piplani expressly teaches away from the examiner's example of having the apices opposing the lumen of a renal artery, stating that:

From the foregoing it can be seen that there has been provided a graft having a bifurcation in which the main body of the graft as well as the legs are firmly attached in the arterial vessels so that they accidentally cannot become dislodged from the location in which they are fixed in the arterial walls. The method which is utilized for deploying the graft with legs is relatively simple and can be accomplished within a relatively short period of time. The major and minor deployment devices which are utilized in the procedure are constructed in such a manner that they are easy to utilize with a minimum of training. The use of a folded-over second leg of the graft in the capsule makes it unnecessary to move the main body of the graft as high in the aorta as would be otherwise necessary in order to permit the second leg of the graft to clear the aortic bifurcation to thereby permit the second leg to be placed in the second iliac artery. *Thus, the risk incurred by moving the graft and its capsule and any associated debris past the renal arteries located well above the aortic bifurcation is greatly reduced thereby reducing the chance of occluding the renal arteries and causing embolization to the renal arteries.* [Piplani, last paragraph of the specification; bold and italics added for emphasis.]

Moreover, the example expressly provided by Piplani's Fig. 19 is one in which the apices do not extend across a lumen, just like Piplani's other examples of Figs. 13, 14, 15, and 16. Therefore, the limitation of apices extending across a lumen does not necessarily occur and therefore is not inherent within the meaning of 35 USC 102.

Moreover, having Piplani's apices extending to a bifurcation would be non-functional. Piplani, for example, Fig. 8 and the top of Fig. 4 show hooks 142, 208, at the apices. See the discussion at Piplani column 5 lines 64-67 indicating the purpose of the hooks it to penetrate into the vessel wall. The hooks address the known problem of securing in place a graft against movement of the graft in a vessel. However, what the examiner proposes would position some of those hooks on a first side of the graft facing the lumen of a vessel such that those hooks would not press against tissue and therefore could not hook into a vessel wall. Moreover, hooks on the opposite second side of the same end of the graft from the hooks on the first side opposing the lumen would not have a tension generated from the spring limitation due to the hooks on the first side, thereby reduce the chance that the hooks on the second side would in fact penetrate into a vessel wall to thereby secure the graft against movement in the vessel. In sum, the examiner's example would seem to be non-functional, and therefore for this additional reason, not inherent.

In contrast, independent claim 12 recites "wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel," thereby defining apices that extend across a lumen of the second vessel without occluding the lumen of the second vessel. Since Piplani neither expressly nor inherently discloses those limitations, the rejection of independent claim 12 under 35 USC 102 as inherently anticipated by Piplani is improper, and should be reversed.

Similarly, independent claim 20 recites "wherein the first end is reinforced with a wire member which has a plurality of apices extending beyond at least a portion of the first end and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel," thereby defining apices that extend across a lumen of the second vessel without occluding the lumen of the second vessel. Since Piplani neither

expressly nor inherently discloses those limitations, the rejection of independent claim 20 under 35 USC 102 as inherently anticipated by Piplani is also improper, and should be reversed.

d. **Dependent Claims 13-16, 19, and 25-36**

Regarding the dependent claims, the examiner states that:

*As to claims 25-30, wire structure (126 or 127) has a shape that is clearly generally sinusoidal or zig-zag even though it is not a perfect sine wave. As to claims 31-36, Piplani et al. disclose first and second wires (the lengths of platinum wires described in col. 5, lines 23-27).*

1. **Claims 25-30 - generally sinusoidal or zig-zag**

In reply, the appellant disagrees with the examiner regarding claims 25-30. The examiner is authorized to examine based upon the broadest reasonable interpretation of the claims in view of the specification. Dependent claims at issue recite for example that the wire structure "comprises a wire having a shape that is generally closed sinusoidal or zig-zag." The specification show in figure, specifically figures 2, 3, 5, and in detail in figures 6 and 7 wire that are closed by twisting their ends together to provide the sole deviation from a sinusoidal or zig-zig shape. The word "generally" literally means, "with some exceptions". The figures in this application show the exceptions relate to (1) the termination of the ends of the wire and possible lack of conformance to a pure sine wave form. No figure in this application show little loops of the kind shown in Piplani's figures that are in Piplani's figures for the purpose of providing springiness. Moreover, this application expressly teaches that the wire forms are malleable, deformable, non-springy, material. In contrast, Piplani teaches that his wires are designed to spring into position when removed from a restraining sheath, the so called "self expanding" type of stent/graft structures.

The examiner asserts that Piplani shows "*wire structure (126 or 127) has a shape that is clearly generally sinusoidal or zig-zag*". However, elements 126, 127 are not accurate representations of the morphology of Piplani's wire structures since they are small elements in an overall schema view in for example Piplani's figure 19. The structural features of elements 126,

127 are shown in more detail in for example Piplani's figure 8 and the top and bottom ends of Piplani's figure 4. Both of these figures show the spring loops and hooks at apices of Piplani's wires. Clearly, no reasonable person would understand that features claimed in this application as "generally" sinusoidal or zig-zag would include clearly non-sinusoidal morphological changes as drastic as complete loops at each apice, in view of (1) the morphological differences between the shapes shown in this application compared to Piplani and (2) the different purposes of the different morphology of the wire forms (deformability into position versus springing into position) taught in this application and in Piplani. Therefore, the examiner's assertion that claims in this application reciting generally sinusoidal or generally zig-zag wire forms read upon what is shown in Piplani's Fig. 8 is broader than any broadest reasonable interpretation in view of the specification. Therefore, Piplani does not anticipate under 35 USC 102 the subject matter defined by claims 25-30. For this additional reason, the 102 rejections of claims 25-30 are improper and should be reversed.

**2. Claims 31-36 - Additional Wires Not at an End of the Prosthesis**

The appellant notes that the examiner fails to assert that Piplani discloses any additional wires not at an end of the prosthesis, as defined by claims 31-36. Therefore the examiner has not rebutted the presumption that claims 31-36 are not anticipated by Piplani.

**5. The Rejections of Claims 12-16, 19, 20 and 25-36 Under 35 USC 103 as Obvious in view of Piplani are Improper and Should be Reversed**

**a. Independent claims 12 and 20**

With all due respect, the examiner has not presented a rationale for a grounds for rejection of these claims under 35 USC 103. This is not a case where the examiner has arguably made a prima facie case that rebuts the presumption of novelty and non-obviousness defined by the introductory clause of 35 USC 102. Instead, there an assertion of obviousness without any reference or support from prior art evidence.

The generally requirements for a rejection under 35 USC 103 are:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non obviousness, these inquiries may have relevancy. [Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 466-67 (1966).]

Graham says that " Against this background, the obviousness or non obviousness of the subject matter is determined." The CCPA and then the CAFC have long specified that determining obviousness requires both specific facts present in the prior art and reasoning showing why those facts would have motivated on in the relevant art to provide what is being claimed. Often quoted is In re Rouffet, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998), which states in one relevant part that:

This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In this case, the Board relied upon none of these. Rather, just as it relied on the high level of skill in the art to overcome the differences between the claimed invention and the selected elements in the references, it relied upon the high level of skill in the art to provide the necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in

complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Rouffet's invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight. This court forbids the use of hindsight in the selection of references that comprise the case of obviousness. See In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Lacking a motivation to combine references, the Board did not show a proper prima facie case of obviousness. This court reverses the rejection over the combination of King, Rosen, and Ruddy. [In re Rouffet, 149 F.3d 1350, \_\_\_, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).]

In this case, the examiner has not identified a level of skill, and most importantly has not identified any evidence of a prior art teaching providing a motivation to modify to provide apices extending across a lumen. In fact, all the examiner has stated in support of the rejections under 103 is that, "Alternatively, it would have been obvious that the apices are capable of being located across a lumen of a second vessel for this reason. " The examiner's antecedent for "this reason" appears to be the examiner's prophetic example that, "For example, viewing figure 19, if the prosthesis 20 is inserted into a patient who has arteries (shown in figure 19 extending laterally near the top of the figure) which are closer to the aortic bifurcation 221 than the example shown in figure 19, than the apices 132 on wire structure 126 would be located across the lumen of each of the laterally extending arteries. " Skipping the issue of level of skill, the examiner's prophetic example is not a motivation to do anything, and it is not prior art. It is instead a modification of prior art evidence disclosed in Piplani, proffered by the examiner. However, the prior art evidence, Piplani's disclosure, does not disclose or suggest the examiner's prophetic

example, which is instead a modification of what Piplani discloses in which Piplani's graft is placed in a patient such that the apices at the top of the graft extend into or across the lumen opening of a renal artery. Piplani contains no suggestion to do that.

Moreover, as stated in response to the 102 rejections, Piplani teaches that a problem it avoids is in fact exactly what the examiner's prophetic example defines. The last paragraph of Piplani's specification explains that very clearly, stating that:

The use of a folded-over second leg of the graft in the capsule makes it unnecessary to move the main body of the graft *as high in the aorta as would be otherwise necessary in order to permit the second leg of the graft to clear the aortic bifurcation* to thereby permit the second leg to be placed in the second iliac artery. *Thus, the risk incurred by moving the graft and its capsule and any associated debris past the renal arteries located well above the aortic bifurcation is greatly reduced thereby reducing the chance of occluding the renal arteries and causing embolization to the renal arteries.*

Given the lack of a prima facie case for rejection, and given the clear teachings in the only applied prior art document, Piplani, relied upon in the obviousness rejections, in fact rebutting the desirability of the examiner's prophetic example, it is clear that there is no motivation to modify Piplani to provide for apices extending across a lumen of a vessel. Since both independent claims 12 and 20 define apices extending across a lumen, the rejections of claims 12 and 20 under 35 USC 103 are improper and should be reversed.

**b. Dependent claims 13-16, 19, and 25-36**

The examiner provides no reasoning why claims 25-30 and 31-36 would be obvious in view of Piplani. Accordingly, there appears to be no prima facie case against these claims, or even an assertion that Piplani would suggest the features defined by these claims. Therefore, if the panel finds that claims 25-30 and 31-36 are not anticipated by Piplani, it should stop here, and reverse the rejections.

In any case, claims 25-30 define generally sinusoidal or zig-zags and claims 31-36 define additional wires not at an end of the prosthesis. As noted above, Piplani does not disclose the limitations of any of these claims. Piplani discloses coiled spring type structures to support the springy nature required by Piplani's graft to hook into the vessel walls. Therefore, there would be no reasonable motivation to modify Piplani to remove the coils providing much of the springiness to Piplani's hooks. Moreover, there is nothing in Piplani to suggest additional wires not located at the end of the graft.

For all of the foregoing reasons, the rejections of claims 25-36 as obvious in view of Piplani are improper and should be reversed.

**6. The Examiner's Rejections of Claims 17 and 18 Under 35 USC 103(a) as Being Unpatentable Over Piplani in View of Kornberg are Improper and Should be Reversed**

The examiner rejects claims 17 and 18 under 35 USC 103(a) as allegedly being unpatentable over Piplani in view of Kornberg, stating that:

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piplani et al. (5,489,295) *in view of Kornberg (4,617,932)*. Piplani et al. fail to disclose stainless steel or plastic as the material for the wire structure. However, it is old and well known to use these materials in order to obtain the advantage of making the device biocompatible as well as strong. *For example, Kornberg teaches that such materials may be used for the wire structures 16 and (14, 15) in an aortic graft for these reasons (col. 4, lines 8-17, 25-29 and 48-49).* It would have been obvious to use either of these materials for the Piplani et al. wire structures so that it too would have these advantages. [Office action mailed August 23, 2005 page 4 lines 13-24; text added relative to the rejection of claims 17 and 18 based solely upon Piplani in the prior office action in bold and italics.]



In response, the appellant notes that Kornberg fails to make up for the deficiencies regarding claim 12 noted above.. Claims 17 and 18 depend from claim 12 and are allowable for the reasons applicable to claim 12.

**7. The Examiner's Rejections of Dependent Claims 21-36 Under 35 USC 102(e) as Anticipated by or, in the Alternative, Under 35 USC 103(a) as Obvious Over USP 5,665,115 to Cragg are Improper and Should be Reversed**

Cragg discloses an intraluminal stent formed from a wire shaped into a continuous helix of zig zags. See the abstract which states that:

A intraluminal stent and graft includes a stent made of a continuous helix of zig-zag wire and loops which connect adjacent apices of the wire. The stent is compressible and self-expandable substantially to a pre-compressed configuration. The device also includes a graft secured to the stent and made of a suitable biocompatible material...

and look at figure 1, which displays the helix.

The examiner rejects claims 21-36 under 35 USC 102(e) as allegedly anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Cragg, stating that:

Claims 21-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cragg (5,665,115). Cragg discloses a prosthesis (figures 7-9) wherein at least one of the first and second ends is provided with a wire structure 11 which has a plurality of apices extending beyond at least a portion of the corresponding end (in the embodiment in which the graft 13 is shorter than the wire helix as described in col. 3, lines 29-31), wherein the apices are formed from malleable material that it not substantially resilient (col. 4, lines 24-26). The apices are inherently capable of being located across a lumen of a second vessel. Alternatively, it would have been obvious that the apices are capable of being located across a lumen of a second vessel. As to

claims 31-36, Cragg discloses first and second wires (the wire hoops of wire body 11 which are located near the middle of the prosthesis). [Office action mailed August 23, 2005 page 5 lines 3-18.]

Claims 21-36 are dependent claims that depend variously from claims 12 and 20.

In response, the appellant respectfully submits that both the examiner's inherency argument and the examiner's obviousness argument based upon Cragg are just as inappropriate and defective as the examiner's corresponding argument for rejecting claims 12 and 20 over Piplani. In fact, they are the same argument based upon the same operative facts.

There is no disclose in Cragg that a "plurality of apices *extend across a lumen of the second vessel without occluding the lumen of the second vessel*." The examiner's basis for rejection of claims based upon Cragg is in fact identical to the examiner's basis for rejection claims under 102 and 103 in view of Piplani. That basis is merely the examiner's assertion that "The apices are inherently capable of being located across a lumen of a second vessel." Since the appellant has fully explained in connection with the rejections of Piplani herein above why that the examiner's assertion is legally insufficient and in fact incorrect, the appellant relies on that reasoning in response to the rejections based upon Cragg. For all of the reasons relating to claims 12 and 20 presented in response to the rejections based upon Piplani, claims 12 and 20 are neither anticipated nor suggested by Cragg. Therefore, the rejections of dependent claims 21-36 via their dependency on either claim 12 or claim 20 based upon Cragg are improper and should be reversed for the same reasons.

The examiner also asserts that "[a]s to claims 31-36, Cragg discloses first and second wires (the wire hoops of wire body 11 which are located near the middle of the prosthesis)."

That statement is incorrect. As clearly explained by Cragg's abstract, the wire hoops of wire body 11 are all part of the same wire formed into a helix and extending to both ends of the stent. Thus, Cragg does not disclose more than a single wire, and certainly Cragg does not disclose what is claimed by claims 31-36, such as a wire that is "not at an end of said prosthesis". For this additional reason, the rejections of claims 31-36 is improper and should be reversed.

As to claims 21-30, the examiner provides no correlation of teachings in Cragg with what

these claims define. Therefore, the examiner provides no more than a bare allegation that claims 21-30 are unpatentable. Such a bare allegation, an allegation, without citation to the prior art or the claimed limitations, does not make a prima facie case. Accordingly, the panel should dismiss and reverse those rejections per curium.

**8. The Examiner Noting of Prior Art The Examiner Considers Pertinent**

The examiner notes prior art considered pertinent, stating that:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Although already of record, note col. 6, lines 38-42 of Barone (5,360,443) and Palmaz (4,733,665) which discloses wire member 71 in figures IA and 1B. [Office action mailed August 23, 2005 page 5 lines 19-23.]

In response, the appellant notes the examiner makes no rejections based upon this art.

**H. 37 CFR 41.37 (c)(1)(viii) Claims Appendix**

Appendix I is attached which contains a copy of the claims involved in the appeal.

**I. 37 CFR 41.37 (c)(1)(ix) Evidence Appendix**

There is no additional evidence included with this appeal brief.

**J. 37 CFR 41.37 (c)(1)(x) Related Proceedings Appendix**

One of the patents having some of the same priority claims is being asserted in infringement litigation in a district court. However, that litigation relates to claims directed to a graft comprising two pieces. Claims in this application do not define a graft defining two pieces. Accordingly, the undersigned believes that litigation not relevant to the claims in this application.

**IV. 37 CFR 41.37 (c)(2)**

This brief does not include any new or non-admitted amendment.

V. **37 CFR 41.37 (d)**

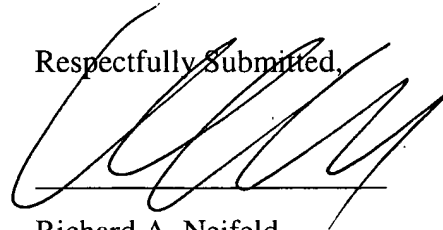
This appeal brief complies with all the requirements of paragraph (c) of this section.

VI. **37 CFR 41.37 (e)**

The appellant herewith timely files the appeal brief.

11/21/2005  
DATE

Respectfully Submitted,



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RLB/DHS/BTM/ran

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**Appendix I - CLEAN COPY OF CLAIMS PENDING IN THE APPLICATION**

Claims 1-11. (Cancelled)

12. (Original)            A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:  
a first end,  
a second end, and  
wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel.

13. (Currently Amended)            The prosthesis of claim 12 wherein the prosthesis is bifurcated.

14. (Currently Amended)            The prosthesis of claim 12 wherein the first vessel is an aorta and the second vessel is a renal artery.

15. (Currently Amended)            The prosthesis of claim 12 wherein the prosthesis has a tubular shape.

16. (Currently Amended)            The prosthesis of claim 12 wherein the wire structure is formed of a metal.

17. (Currently Amended)            The prosthesis of claim 12 wherein the wire structure is formed of a stainless steel.

18. (Currently Amended)            The prosthesis of claim 12 wherein the wire structure is formed of a biocompatible plastic.

19. (Currently Amended) The prosthesis of claim 12 wherein the prosthesis is for treatment of aneurysms or occlusive diseases.

20. (Original) A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

a first end adapted for placement adjacent to a junction between the first vessel and the second vessel, and

a second end,

wherein the first end is reinforced with a wire member which has a plurality of apices extending beyond at least a portion of the first end and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel.

21. (Previously Presented) The prosthesis of claim 12 wherein said plurality of apices are formed from malleable material.

22. (Previously Presented) The prosthesis of claim 12 wherein said plurality of apices are formed from a material that is not substantially resilient so that said plurality of apices have to be physically expanded in order to press against an inner surface of said first vessel.

23. (Previously Presented) The prosthesis of claim 20 wherein said plurality of apices are formed from malleable material.

24. (Previously Presented) The prosthesis of claim 20 wherein said plurality of apices are formed from a material that is not substantially resilient so that said plurality of apices have to be physically expanded in order to press against an inner surface of said first vessel.

25. (Previously Presented) The prosthesis of claim 12 wherein said wire structure comprises a wire having a shape that is generally closed sinusoidal or zig-zag.

26. (Previously Presented) The prosthesis of claim 25 wherein said shape is generally closed sinusoidal.

27. (Previously Presented) The prosthesis of claim 25 wherein said shape is generally closed zig-zag.

28. (Previously Presented) The prosthesis of claim 20 wherein said wire structure comprises a wire having a shape that is generally closed sinusoidal or zig-zag.

29. (Previously Presented) The prosthesis of claim 28 wherein said shape is generally closed sinusoidal.

30. (Previously Presented) The prosthesis of claim 28 wherein said shape is generally closed zig-zag.

31. (Previously Presented) The prosthesis of claim 12 further comprising at least a first wire not at an end of said prosthesis.

32. (Previously Presented) The prosthesis of claim 31 further comprising at least a second wire not at an end of said prosthesis.

33. (Previously Presented) The prosthesis of claim 12 further comprising a plurality of wires arrayed along a length of said prosthesis.

34. (Previously Presented) The prosthesis of claim 20 further comprising at least a first wire not at an end of said prosthesis.

35. (Previously Presented) The prosthesis of claim 34 further comprising at least a second wire not at an end of said prosthesis.

36. (Previously Presented) The prosthesis of claim 20 further comprising a plurality of wires arrayed along a length of said prosthesis.

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